

Notice of Allowability

Application No.

10/635,040

Applicant(s)

TOMORI ET AL.

Examiner

Anthony J. Paviglianiti

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Response to Restriction on 09 June 2005.
2. ☒ The allowed claim(s) is/are 2.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of the:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date <u>7/31/03; 11/4/03 & 6/30/04</u> . | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

DETAILED ACTION

Claims 1 – 12 were pending in the instant application and were subject to a restriction requirement dated April 20, 2005 (see below). **Claims 1** and **Claims 3 – 12** were cancelled by Examiner's Amendment with authorization by the Applicant. Therefore, **Claim 2** is pending in the instant application. An Examiner's Amendment follows the analysis below.

Priority

This application is the National Stage Application (35 U.S.C. §371) (effective filing date July 31, 2003) of PCT/JP02/00804 (filing date February 1, 2002).

Acknowledgement is made of applicant's claim to foreign priority under 35 U.S.C. §§119(a) – (d), by Japanese patent application No. 2001-026374, with filing date February 2, 2001.

Information Disclosure Statement

The Information Disclosure Statements filed on July 31, 2003, November 4, 2003, and June 30, 2004, are in compliance with 37 C.F.R. §1.97, and were considered by the examiner.

Election/restriction and response to traverse

Applicant's written "Response to Restriction Requirement," dated June 9, 2005, has been entered, electing the invention of **Group II (Claim 2)** and the compound "1-acetyl-7-nitro-5-ethoxycarbonylmethyl-4,6-dimethylindoline."

Accordingly, **Claims 1** and **Claims 3 – 12** were withdrawn from further consideration as being drawn to a non-elected invention pursuant to 37 C.F.R. §1.142(b).

The restriction requirement was made with traverse on grounds that the restriction requirement did not state the scope of the invention to be searched for applicant's consideration.

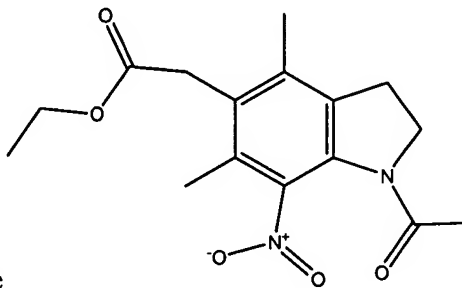
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Examiner agrees with applicant's argument that the scope of the invention which was searched is relevant to this analysis, and provided a synopsis of this information to applicant during a telephone conversation about the claims on August 5, 2005. A written description of the scope of the art which was searched for this invention is found below.

Scope of Prior Art Searched

1) *The elected compound*

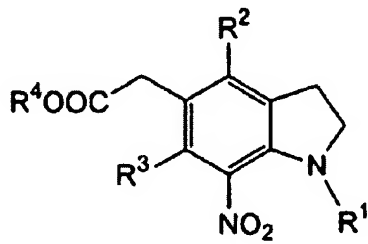
The chemical compound elected by applicant, "1-acetyl-7-nitro-5-ethoxycarbonylmethyl-



4,6-dimethylindoline," having the structure , was searched in the applicable art, and is free of the prior art of record.

2) *Expansion of search of prior art*

The search of the art was expanded beyond the elected compound corresponding to



compounds of formula (II), as depicted in **Claim 2**, wherein **R¹** was searched as a "protective group for the amino group" (as defined in the Specification at page 8, lines 12 – 23, and at page 9, lines 1 – 37); **R²** and **R³** were searched as a "lower alkyl group" (as defined in the Specification at page 10, lines 3 – 11); **R⁴** was searched as a hydrogen atom or as a "protective group for the carboxyl group" (as defined in the Specification at page 10, lines

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13 – 26 and p. 11, lines 1 – 20); and searched for salts and “amide” derivatives (as defined in the Specification at p. 11, lines 22 – 37, and p. 12, lines 1 – 7 [“amide”] and p. 12, lines 9 – 38 [salts]). The closest prior art found in the course of the search is described below.

Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 C.F.R. §1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Agreement for the following examiner's amendment as to **Claims 1 and 3 – 12** was reached in a telephone interview with Marshall J. Chick, Esq., on August 5, 2005, and authorized by Mr. Chick. The agreement and authorization are also summarized on the Telephone Interview Summary Form (PTOL-413) dated August 5, 2005.

The claims in the application have been amended as follows:

Delete **Claim 1**.

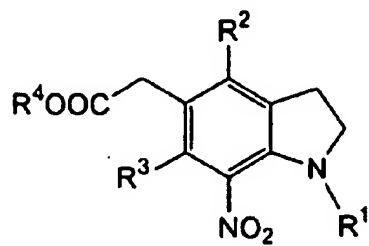
Delete **Claims 3 – 12**.

The deleted claims were cancelled by applicant without prejudice to pursue in a future continuing or divisional application. It is not necessary for applicant to provide a separate record of the substance of the telephone interview of August 5, 2005.

Reasons for Allowance

The following is an examiner's statement of reasons for allowance: The present invention is directed to chemical synthetic intermediates of formula (II),

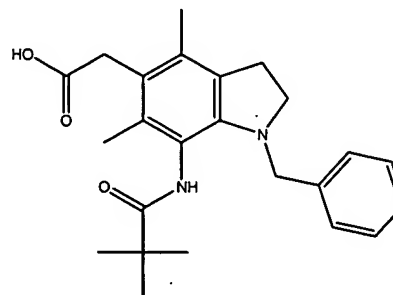
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, as depicted in **Claim 2** of the present application, wherein **R¹** is a “protective group for the amino group”; **R²** and **R³** are the same or different and each represents a “lower alkyl group”; **R⁴** is a hydrogen atom or a “protective group for the carboxyl group”; a salt or an amide derivative thereof.

Specifically, the synthetic intermediates of formula (II), as limited in **Claim 2**, were found to be free of the prior art because of the particular combination of substituents on the indoline ring; i.e., their novelty arises from the limitation of a nitro (NO₂) group at the 7-position, combined with required “lower alkyl” groups at the 4- and 6-positions, as well as an acetic acid, acetate (or acetamide) substituent at the 5-position, and an amino-protecting group at the 1-position (i.e., bonded to the indoline ring’s nitrogen atom). When the above limitations were imposed, even the broadest interpretation of the limitations of substituent groups **R¹**, **R²**, **R³** and **R⁴** were not anticipated nor rendered obvious by known chemical compounds in the prior art.

The closest applicable prior art is the compound disclosed in **U.S. Patent No. 6,063,806** (Kamiya, et al.), issued May 16, 2000, which disclosed the compound N-(5-carboxymethyl-4,6-



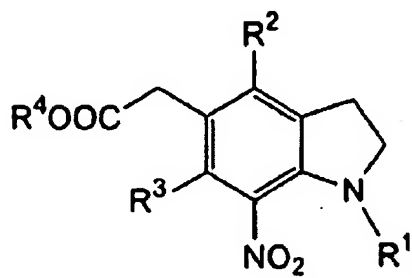
dimethyl-1-benzyl-indolin-7-yl)-2,2-dimethylpropanamide,

(see

U.S. Patent No. 6,063,806 at col. 37, Table 8, “Example 115”). This compound meets many of

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the limitations of formula (II) in **Claim 2** of the present invention,



, where R^1 is a benzyl group (which is within the scope of an “amino protecting group” – see Specification at p. 9, line 19); R^2 and R^3 are each a methyl group; and R^4 is hydrogen; however, the prior art differs from the compounds of the present invention because the substituent at the 7-*position* of the indoline ring in the prior art is “– $\text{NC}(\text{O})\text{C}(\text{CH}_3)_3$,” instead of the requisite NO_2 group of the present invention. Nor would the prior art meet the alternative limitation of **Claim 2** as an “amide derivative” of formula (II), as the Specification expressly defines the term “amide” as “...a group which is produced by *substitution of a carboxyl group* with an amino group...” [emphasis added] (Specification at p. 11, lines 22 – 23). Thus, the compound disclosed in U.S. Patent No. 6,063,806, which was determined to be the closest prior art, does not meet all of the limitations required for the synthetic intermediate compounds of formula (II) in **Claim 2** of the present invention.

Therefore, based on the analysis above, **Claim 2** is neither anticipated nor rendered obvious over the prior art of record, and is allowable.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled “Comments on Statement of Reasons for Allowance.”

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Conclusion

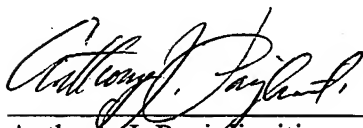
Claim 2 is allowed.

Claims 1 and 3 – 12 were cancelled by Examiner's Amendment authorized by applicant.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Anthony J. Paviglianiti** whose telephone number is **(571) 272-3107**. The examiner can normally be reached on Monday-Friday, 8:30 a.m. - 5:30 p.m.

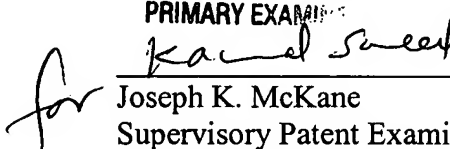
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached at (571) 272-0699. **The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300. Please note that this is a new central FAX number for all official correspondence.**

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Anthony J. Paviglianiti
Patent Examiner
TC-1600, Art Unit 1626

KAMAL A. SAEED, PH.D.
PRIMARY EXAMINER



for Joseph K. McKane
Supervisory Patent Examiner
TC-1600, Art Unit 1626